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DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

**JOSE GONZALO ZAVALITA, M.D.
DENIAL OF APPLICATION**

On March 2, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause (Order) to Jose Gonzalo Zavaleta, M.D. (Applicant), of Alexandria, Louisiana (La.). The Order proposed the denial of Applicant's pending applications for DEA Certificates of Registration as a practitioner, which he filed on April 19, 2010 (Control Number W10020882C) and on December 9, 2010 (Control Number W10078290C), for the registered location of 1217 Willow Glen River Road, Alexandria, La., on the ground that his registration would be "inconsistent with the public interest." Order at 1 (citing 21 U.S.C. § 823(f)).

The Show Cause Order incorporated by reference the allegations of a previous Show Cause Order which had been issued on February 23, 2009; a copy of the latter was attached to the second Show Cause Order. *Id.* at 1-2. The first Show Cause Order had alleged that Applicant voluntarily surrendered his DEA Certificate of Registration, BZ5998250, on March 26, 2008, after being charged with six counts of prescribing controlled substances beyond authority and accepted medical treatment, in violation of La. Rev. Stat. Ann. § 40:971 (C)(1)(2008) (effective Aug. 15, 2006). *Id.* The first Order further alleged that Applicant prescribed controlled substances to undercover agents with "cursory or no medical examinations, and without a legitimate medical purpose in violation of 21 U.S.C. § 841(a)(1)," including a total of 75 dosage units of hydrocodone (including Lortab and/or Lorcet), which are schedule III narcotics; 20 dosage units of Xanax, a schedule IV controlled substance; and six ounces of

Phenergan with codeine, a schedule V narcotic cough syrup. Id. Finally, the first Order alleged “[Applicant] facilitated the undercover officers’ procurement of drugs by fraudulent means” when he advised them to “provide false medical information” to justify “illegitimate prescriptions.” Id. at 2.

In addition to these allegations, the Second Show Cause Order alleged that on June 24, 2010, Applicant had entered into a consent agreement with the Louisiana State Board of Medical Examiners which had found “that reasonable cause existed for recommending that a formal Administrative Complaint be filed against [him], charging [him] with violation of the Louisiana Medical Practice Act.” Show Cause Order at 2. The Second Show Cause Order further alleged that “[t]o avoid the filing of a formal Administrative Complaint, [Applicant] entered into a consent order with the Board . . . in which [he] accepted a public reprimand and various conditions [were] place upon [his] medical license.”

On March 7, 2011, the Second Show Cause Order, which also notified Applicant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing so, and the consequence if he failed to do either, was served on Applicant by certified mail addressed to him at the address listed on his second and third applications. Id. at 2 (citing 21 CFR 1316.47; 21 CFR 1301.43). Since service of the Second Order, more than thirty days have now passed and neither Applicant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. See 21 CFR 1301.43(b)-(d). Accordingly, I find that Applicant has waived his rights to a hearing or to submit a written statement. Id. 1301.43(d). I therefore issue this Decision and Final Order without a hearing based on relevant material contained in the investigative record submitted by the Government. I make the following findings.

FINDINGS

On July 27, 2011, I issued a Decision and Final Order denying Respondent's application which he filed on July 28, 2008 and which was the subject of the first Show Cause Order. See Jose Gonzalo Zavaleta, M.D., 76 FR 49506 (Aug. 10, 2011). Therein, I made extensive findings that are res judicata in this proceeding.

Applicant was previously the holder of DEA Certificate of Registration, BZ5998250, which authorized him to dispense controlled substances in schedules II through V as a practitioner at the registered location of 5629 Jackson Street Ext., Alexandria, Louisiana. 76 FR 49506. However, on March 26, 2008, concurrent with Applicant's arrest on state drug charges (the circumstances of which are set forth below), he voluntarily surrendered his registration. Id. Applicant's registration was then retired by DEA on March 27, 2008. Id.

On July 28, 2008, Applicant applied for a new DEA registration as a practitioner in schedules IV and V; this application was denied by my Order of August 10, 2011. Id. On April 19, 2010, Applicant filed a second application for a practitioner's registration, seeking authority to handle controlled substances in schedules II through V at the registered location of Rapides Primary Health Care Center, 1217 Willow Glenn River Rd., Alexandria, La. 71302. GX 6, at 1. On his application, Respondent stated that "the DA made me an offer for a program called PTI and no DEA license for two years. Now, I have completed my part of the deal, meaning I completed two years without [a] DEA license, and now I want my unrestricted DEA license back." Id. On December 9, 2010, Respondent filed a third application; this application was also for the registered location of the Rapides Primary Health Care Center. GX 7.

Applicant first came to the attention of law enforcement on January 17, 2008, when Louisiana State Police received a call from a pharmacist that he had authorized prescriptions for

“excessive amounts of name brand narcotics with no generic substitutions allowed.” 76 FR at 49506. Upon receipt of this information, an undercover state trooper (UC1) visited Applicant’s clinic with audio/video recording equipment on January 23, 2008. Id. When Applicant asked UC1 “why he was there,” UC1 responded by requesting “[h]ydrocodone pain pills.” Id. UC1 “initially denied that he was in pain but, after negotiating with [Applicant], he agreed to falsely state that he was suffering from a sexually transmitted disease,” and Applicant recorded this false information in UC1’s medical file. Id. Then, Applicant, without any physical examination to verify the claim of illness or symptoms, wrote prescriptions for 15 Lortab¹ pills and an antibiotic. Id. The undercover agent paid \$100 for the visit. Id.

Five days later, on January 28, 2008, UC1 returned to Applicant’s clinic seeking additional “pain pills.” Id. However, Applicant denied his request for more pain pills “because ‘big brother’ was watching him.” Id.

Thereafter, on January 30, February 8, and February 28, 2008, a second state trooper (UC2) visited Applicant’s clinic in an undercover capacity, while equipped with an audio/video recording device. Id. At UC2’s first visit, Applicant issued her a prescription for hydrocodone,² notwithstanding UC2’s “initially den[ying] she was in pain” and “later stat[ing] she was in pain in order to obtain a prescription for hydrocodone.” Id. At her second visit on February 8, Applicant provided prescriptions for hydrocodone and Phenergan with codeine³, the latter being a cough syrup, “even though she had no cough or congestion and exhibited no such symptoms.” Id. On UC2’s third visit, she requested and obtained from Applicant prescriptions for

¹ Lortab, which is a combination drug containing hydrocodone and acetaminophen, is a schedule III controlled substance. 21 CFR 1308.13(e)(iv).

² Hydrocodone is typically combined with acetaminophen. In this formulation, it is a schedule III controlled substance. 21 CFR 1308.13(e)(iv).

³ Phenergan with codeine cough syrup consists of a combination of promethazine and codeine; it is a schedule V controlled substance. 21 CFR 1308.15(c).

hydrocodone and Xanax.⁴ Id. To justify issuing the prescriptions, Applicant “coached” UC2 about what to say and recorded the coached statements in her medical file. Id. At the undercover visits, Applicant never “require[d] any medical records nor did he conduct any physical examinations.” Id.

On March 20, 2008, after a state court judge issued a warrant for Applicant’s arrest, Louisiana State Police alerted DEA to the investigation and pending arrest. Id. Thereafter, on March 26, 2008, Applicant was arrested and charged with “six counts of prescribing beyond authority and accepted medical treatment, a violation of Louisiana Revised Statute 40:971C(1).” Id. Based on Applicant’s arrest, a DEA Diversion Investigator asked for the voluntary surrender of his DEA registration; Applicant agreed and signed a DEA-104, Voluntary Surrender of Controlled Substance Privileges.⁵ Id. at 49506-07.

Respondent has presented no evidence that he acknowledges his misconduct and accepts responsibility for it.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination "that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f). In making the

⁴ Xanax (alprazolam) is a schedule IV controlled substance. 21 CFR 1308.14(c)(1).

⁵ As part of the record in this matter, the Government submitted a copy of the Consent Order applicant entered into with the Louisiana State Board of Medical Examiners. GX 5. While therein, Applicant “acknowledge[d] that the reported information could provide the Investigating Officer with probable cause to pursue formal administrative proceedings against him for violation of the [Louisiana Medical Practice] Act,” Applicant did not admit to any of the allegations. Id. at 2. Accordingly, I do not rely on the Consent Order to make any findings regarding violations of federal law by the Applicant in prescribing to undercover agents.

However, I find that Respondent had a full and fair opportunity to litigate the allegations of the first DEA Show Cause Order, even if he did not avail himself of it. See Alan H. Olefsky, 76 FR 20025, 20031 (2011); Robert L. Dougherty, 76 FR 16823, 16830 (2011). Accordingly, those findings are res judicata in this proceeding. Olefsky, 76 FR at 20031; Dougherty, 76 FR at 16830.

public interest determination in the case of a practitioner, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

“[T]hese factors are considered in the disjunctive.” Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether . . . to deny an application. Id. Moreover, I am “not required to make findings as to all of the factors.” Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005) (citing Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005)).

In this matter, while I have considered all of the factors, I conclude that it is not necessary to make findings with respect to factors one (the recommendation of the state licensing board), three (applicant's conviction record) and five (such other conduct which may threaten public health and safety). Having previously found that Applicant has committed acts which render his registration “inconsistent with the public interest,” 76 FR at 49507 (quoting 21 U.S.C. §§ 823(f), 824(a)(4)), and Applicant having failed to present any evidence to rebut this conclusion, I will order that his pending applications for registration be denied.

Factors Two and Four – Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is not “effective” unless it is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). This regulation further provides that “an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.” Id.; see also La. Rev. Stat. Ann. § 40:961(33) (2008) (effective Aug. 15, 2004);⁶ La. Rev. Stat. Ann. § 40:1238.2(A) (2008) (effective Aug. 15, 2006).⁷

As the Supreme Court recently explained, “the [CSA’s] prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)); see also La. Rev. Stat. Ann. § 40:1238.2(A) (2008) (effective Aug. 15, 2006).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act “in the usual course of . . . professional

⁶ Louisiana law defines the term “prescription” to mean “a written request for a drug . . . issued by a licensed physician . . . for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.” La. Rev. Stat. Ann. § 40:961(33).

⁷ This statute provides that:

A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. An order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this Section. Any person who knows or should know that he or she is filling such a prescription or order to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section.

La. Rev. Stat. Ann. § 40:1238.2(A).

practice” and to issue a prescription for a “legitimate medical purpose.” Laurence T. McKinney, 73 FR 43260, 43265 n.22 (2008); see also Moore, 423 U.S. at 142-43 (noting that evidence established that physician “exceeded the bounds of ‘professional practice,’” when “he gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,” and “took no precautions against . . . misuse and diversion”). The CSA generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. See Kamir Garces-Mejias, 72 FR 54931, 54935 (2007); United Prescription Services, Inc., 72 FR 50397, 50407 (2007); but see 21 U.S.C. § 829(e)(2)(B) (providing federal standard for prescribing over the internet).

Under the regulation of the Louisiana Board of Medical Examiners, in the treatment of “intractable pain...a physician shall comply” with the Louisiana Pain Rules, including the requirements that a physician perform an “[e]valuation of the [p]atient” and make a “[m]edical [d]iagnosis.” La. Admin. Code tit. 46:XLV.6921(A) (2008). “Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient’s physical and psychological functions, a review of previous diagnostics studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.” Id. (emphasis added); see also Armstrong v. La. State Bd. of Med. Examiners, 868 So. 2d 830, 840 (La.App. 4 Cir. Feb. 18, 2004) (upholding two year suspension of physician’s license; noting that when prescribing controlled substances for relief of non-malignant pain is “unaccompanied by appropriate testing, diagnosis, oversight and monitoring ... the physician falls below generally accepted standards of care”); Pastorek v. La. State Bd. of Med. Examiners, 4 So. 3d 833 (La.App. 4 Cir. Dec. 17,

2008). The Board's rules further require that a "medical diagnosis ... be established and fully documented in the patient's medical record." La. Admin. Code tit. 46:XLV.6921(A)(2) (2008).

Louisiana law also prohibits a physician from "[a]ssist[ing] a patient or any other person in obtaining a controlled dangerous substance through misrepresentation, fraud, forgery, deception, or subterfuge." La. Rev. Stat. Ann. § 40:971.2 (2008) (effective Aug. 15, 2005). It is also unlawful for a physician to "prescribe ... legally controlled substances beyond his respective prescribing authority or for a purpose other than accepted medical treatment of disease, condition, or illness. Id., at § 40:971(C)(1) (2008) (effective Sept. 9, 1988).

As found in my Decision and Order of July 27, 2011, on four occasions, Applicant prescribed drugs containing hydrocodone (including Lortab and/or Lorcet), which are schedule III narcotics; Xanax, a schedule IV controlled substance; and Phenergan with codeine, a schedule V narcotic cough syrup; to Louisiana State Troopers acting in undercover capacities. See 76 FR at 49508. Notably, Applicant issued these prescriptions without conducting a physical examination at any of the visits and the undercover agents received these prescriptions even though they did not demonstrate conditions or symptoms that would justify the prescriptions. Id.

Moreover, both undercover agents initially denied they were in pain, but Applicant assisted the agents in obtaining controlled substances by encouraging them to make false statements. See id. For example, while he denied being in pain, UC1 asked Applicant for "[h]ydrocodone pain pills," and then "negotiate[ed]" with Applicant to "falsely state" he had a sexually transmitted disease. Id. Likewise, Applicant also "coached" the second undercover agent on what to say to "justify issuing the prescriptions and wrote her coached statements in a medical file." Id. Therefore, Applicant failed to establish a physician-patient relationship, lacked a legitimate medical purpose, and acted outside of the usual course of professional

practice in prescribing controlled substances to the undercover agents and thus violated Federal law. See id. (citing 21 CFR 1306.04(a); 21 U.S.C. § 841(a)(1); see also Louisiana v. Moody, 393 So. 2d 1212, 1215 (La. 1981) (holding that physician furnished prescriptions for “other than a legitimate medical purpose” based on evidence showing that prescriptions were issued in response to specific requests of patients and physician did not conduct physical examinations or take medical histories)).

I therefore hold again that granting Applicant’s applications for a new registration “would be inconsistent with the public interest.”⁸ 21 U.S.C. § 823(f). Accordingly, I will order that Applicant’s pending applications be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the applications (Control Numbers W10020882C and W10078290C) of Jose Gonzalo Zavaleta, M.D., for a DEA Certificate of Registration as a practitioner be, and they hereby are, denied. This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER].

Dated: October 8, 2012

Michele M. Leonhart
Administrator

⁸ As found above, Applicant stated in his second application that “the DA made me an offer for a program called PTI and no DEA license for two years,” and that because he has “completed two years without [a] DEA license,” he “want[s] [his] unrestricted DEA license back.” GX 6. Respondent has presented no evidence that any DEA official agreed to the deal he made with the district attorney, and in any event, a state official has no authority to bind this Agency. See Edmund Chein, 72 FR 6580, 6590 (2007) (Congress granted the authority to determine whether a registration “is consistent with the public interest” to “the Attorney General of the United States, and that authority has been delegated solely to the officials of [DEA]. State officials therefore lack authority to resolve a matter pending before the Drug Enforcement Administration” and cannot bind this Agency.) (citing 21 U.S.C. § 824, 28 CFR 0.100(b), and Fourth Street Pharmacy v. DEA, 836 F.2d 1137, 1139 (8th Cir. 1988)); see also 21 U.S.C. § 823(f)).

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